

ADDITIONAL FEES

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REMARKS

Claims 1 and 3-13 are in the application. All of the claims are held rejected under § 103(a) for being unpatentable over US Patent 5,844,013 to Kenndoff et al., (“Kenndoff”), US Patent 4,538,603 to Pawelchak and Freeman (“Pawelchak”), and publication WO 89/04649 to Morgan et al., (“Morgan”), each by itself or in combination.

The Applicants request that in view of the foregoing amendments and ensuing remarks, the rejections be withdrawn.

Applicants Invention

The Applicants’ invention is directed toward a light occlusive eye patch having at least two layers of foamed material, with one of said layers having a skin compatible adhesive.

The invention possesses properties that are especially desirable in articles to be used in contact with the human eye for extended periods. For the purpose of illustrating these properties but without limiting the scope of the invention to specific exemplified embodiments, Applicants have disclosed modifications meant to enhance the patch’s mechanical stability. One of such modifications entails applying a non-woven or textile layer to the outermost or top layer. See specification, page 3, ¶ 6.

Another possible approach is to enhance the density of the component foams by adding specific types of fillers. See page 3, ¶5.

Still another approach would be to employ materials that are less prone to becoming soiled and wet, and therefore uncomfortable and esthetically unpleasing.

Therefore, Applicants have chosen materials that, in their native underivatized state, do not imbibe moisture nor are they difficult to clean. Some examples of these starting materials are calendered foams of polypropylene, polyethylene, polyvinylchloride or polyurethane. See page 3, ¶2.

It is in this context that the Applicants respectfully suggest that the claimed patch is indeed patentable over the cited references.

The Examiner's Citation in Kenndoff Cannot Render the Claims Obvious

The Applicants provide an eye patch that is light in weight, and yet has substantial tensile strength and tear resistance. The foam layers in Applicants' patch achieve this by providing several layers of lightweight but tough and flexible material that will not stress the orbital region while occluding it. The Examiner has not provided in this or the previous office action, a clear line of reasoning or evidence by which one with ordinary skill could proceed from a wad of absorbent foam layers, to the claimed eye patch. Instead, the Examiner has relied on the alleged level of skill in the art to arrive at the invention. This is an improper mode of analysis. See MPEP § 2143.01 (*citing Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be relied upon to provide the suggestion to combine references.)).

At the outset, the Applicants acknowledge Examiner's citation to Kenndoff, column 11, lines 5-11, wherein one or more thin layers of foam may be cut into shapes, and applied to a deep wound. This provides a multilayered liquid absorbing wad that can be inserted into a deep wound. The Examiner cites this for teaching or suggesting that foam may be used in layers, and presumably, that this renders the claims obvious.

When Kendoff is viewed in its entirety, the text cited above essentially suggests creating an absorbent wad to use in a sponge-like manner. Even if we assume for argument sake, that one with skill in the art would know that increasing the numbers

of absorbent layers in an article would concomitantly increase the capacity to absorb liquid, this does not even remotely teach or suggest the configuring of foam layers to provide a flexible and lightweight patch that comfortably follows the contours of a person's orbital region. Kendoff's teaching is not even remotely related to the Applicants' claimed invention, and therefore cannot be used to arrive at the Applicants' invention.

It is respectfully suggested that the Examiner has not provided in this or the previous office action, a clear line of reasoning or evidence by which one with ordinary skill could proceed from a wad of absorbent foam layers, to the claimed eye patch. Accordingly, it is respectfully suggested that a *prima facie* case of unpatentability has not been made. MPEP § 2142.

Kenndoff's Hydrogel is Clearly Distinct and Cannot Render the Claims Obvious

Obviousness can only be established where there is found some explicit or implicit motivation or suggestion in the references themselves or in the knowledge of one with ordinary skill in the art, to make the proposed modification of the references. MPEP § 2143.01.

"The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000) (Emphasis added).

It is noted that it is not sufficient to establish *prima facie* obviousness to merely show that references can be modified or combined. Neither is it sufficient to demonstrate that the asserted modification is within the capabilities of one with ordinary skill in the art. The proposed modification must arise from a reference's suggestion or motivation to do so. MPEP § 2143.01.

Kenndoff discloses a hydrophilic polyurethane gel foam for treating deep wounds. These hydrogels absorb and bind aqueous fluids, such as those emitted by a wound during treatment and healing. The key feature of Kenndoff is the high absorbent capacity of the material.

To achieve this result, Kenndoff uses a polyhydroxy compound as a starting material to react with, *inter alia*, polyisocyanate. This yields a polyurethane that has an abundance of hydrophilic hydroxyl groups that impart the moisture absorbing property. In addition, Kenndoff teaches the addition of other various water absorbing materials. See column 7, lines 20-29; tables in column 8, and elsewhere.

The claimed patch is different from Kenndoff. Neither Applicants' claims nor disclosure recite the inclusion or desirability of a hydrophilic eye patch foam material. As opposed to wound dressings, it would likely result in an inferior eye patch that would quickly become wet and soiled. Such a patch would inordinately and unnecessarily limit the wearer's activities while trying to strengthen the weaker eye. This helps to defeat the purpose of the eye patch therapy.

Accordingly, there cannot be any reasonable motivation or suggestion to modify Kenndoff or to modify its teachings in a manner that would lead to the claimed invention.

The Applicants respectfully solicit withdrawal of the rejection over Kenndoff.

Pawelchak ('603) and Morgan Do not Render the Claims Obvious When Properly Viewed in Their Entirety

The patentability of a claim is determined by viewing the invention as a whole. "Casting an invention as combination of old elements leads improperly to an analysis of the claimed invention by the part, not by the whole." Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc., 807 F.2d 955 (Fed. Cir.1986).

Similarly, the references themselves must also be viewed in their entirety, i.e., as a whole, including portions that teach away. MPEP § 2143.02. The Applicants' suggest that the Examiner has not followed these guidelines, and instead, has picked and chosen the elements upon which the rejection is based, using the Applicants' claims as a blueprint.

Morgan's patch relied entirely on Squibb's commercial wound dressing that was covered by the Pawelchak patent (see Morgan, page 5, line 8). Morgan literally physically combined his concept with Pawelchak's teachings by cutting a rounded profile of the Squibb dressing, and applied to it a black pad (14) and a hydrophilic adhesive (20). Thus, Morgan provides an excellent real-life example of relying on Pawelchak in order to arrive at an eye patch. The result is that they do not teach all of the claim limitations.

Applicant's suggest that this is strong evidence that it is not *prima facie* obvious to combine Pawelchak into an eye patch, and to obtain an article comprising at least two foam layers. The combined references provide an eye patch with only one flexible foam layer. If more than one layer were obvious it is likely that Morgan would have disclosed and claimed such an embodiment. In contrast, Morgan does not even disclose the desirability of applying one or more additional foam layers. Therefore, there cannot be any reasonable suggestion or motivation to combine Pawelchak and Morgan to approximate the claimed invention.

However, what is also critical in implementing the "references as a whole" analysis, is that Morgan also does not suggest the omission of the non-foam layers he discloses – e.g., the polymer film (16) and the thick hydrogel adhesive (20). Yet, the Examiner's rejection seems predicated on the assumption that it is proper to multiply certain elements (e.g., foam layers) and ignore others (e.g., polymer film, hydrogel adhesive) in order to formulate a rejection. This violates Fed Circuit's holdings cited above, as well as PTO guidelines. MPEP § 2143.01.

The Examiner specifically indicates that the rejection is "pointing out to", *inter alia*, that Pawelchak teaches an adhesive layer contacting the wound and

surrounding skin. Column 11, lines 16-18. Further, WO '649 to Morgan is applied for showing that an adhesive layer may be applied to a foam layer. These are merely recitations of elements plucked from the references as a whole and used out of context. Aside from being improper, it also does not yield each of the Applicants' claimed limitations.

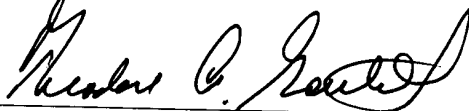
The Applicants respectfully suggest that the Examiner has not properly applied the references. The teachings of Morgan already disclose what one with skill in the art would conceive based on Pawelchak, and this does not approximate the claimed invention.

CONCLUSION

In view of the foregoing amendments and remarks, the Applicants respectfully request reconsideration of the application, and allowance of the claims.

Although the Applicants believe the unamended claims were patentable, they have amended the claim 1 to more specifically describe the nature of the patch. It is respectfully suggested that this even further distinguishes the claims from the cited references.

Respectfully submitted



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MARKED UP VERSION OF AMENDED CLAIMS

Claim 1 (three time amended). A light-occlusive eye patch having an upper side and a lower side, comprising at least two layers of foamed material, said at least two layers being a top layer and an inner layer; one side of said inner layer facing said top layer, and the other side of said inner layer being provided with a skin-compatible self-adhesive coating, and wherein at least one of the layers comprises a black-colored, light-occlusive layer, and further wherein, all of the foamed layers comprise the same foam material.